Remarks

Claims 35-79 are pending. Claims 35-42 are withdrawn. Claims 60-79 are newly added. Claims 43 and 47 have been amended. Support for the amendments to claims 43 and 47 can be found on page 15, lines 10-24, for example. Support for claims 60-62 can be found on page 3, lines 23-26 on page 33 line 17 to page 36, line 17; and on page 21, lines 5-21; support for claims 63-64 can be found on page 7, lines 29-31; support for claim 70 can be found on page 7, line 32 to page 8, line 6; support for claim 71 can be found on page 19, lines 1-11; support for claims 72-79 can be found on page 15, lines 10-24, on page 33 line 17 to page 36, line 17; and on page 21, lines 5-21; Support for claim 67 can be found on page 8, line 2, and in original claim 9; support for claims 66 and 69 can be found on page 72 (abstract); on page 1, lines 16-17; and on page 4, lines 10-14. Support for claims 65 and 68 can be found on page 4, lines 15-20; on page 7, lines 4-5, and on page 7, line 32 to page 8, line 10.

Specification

The specification has been amended on page 1 to reflect the status of parent application serial number 09/170,699. Applicants respectfully request withdrawal of this objection.

Claim Rejections – 35 USC § 112, First Paragraph

Claims 51-59 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly not containing a written description of the claimed invention. Applicants respectfully traverse this rejection. The Office Action alleges that Applicant does not point to specific support for the newly claimed limitations in the response filed with the amendment to the claims on October 6,

2006. However, Applicants respectfully disagree. On page 6 of the Response, applicants specifically state: "Support for claim 51 can be found on page 15, lines 20-23, and on page 16, lines 4-19, for example. Support for claims 52 and 53 can be found on page 16, line 8, for example. Support for claims 54-57 can be found on page 10, lines 20-30, for example. Support for claim 58 can be found on page 10, lines 20-21, for example. Support for claim 59 can be found on page 18, lines 18-20, for example."

The Office Action further alleges that, "although the specification teaches antibodies that bind substantially only to erbB-3 receptor proteins and not to erbB (EGFR) or erbB-2 proteins, antibodies that are specific for erbB-3, the only recitation in the specification drawn to an antibody that binds to erbB-3 and not to erbB or erbB-2 is drawn specifically to Mab E3-1 and the limitation claimed, in the absence of the recitation of the Mab E3-1 broadens the scope of the invention as originally disclosed." Applicants respectfully disagree.

What is sufficient for written description for antibodies was addressed in *Noelle v. Lederman*, 355 F.3d 1343 (Fed. Cir. 2004), which was an interference involving competing claims to human CD40CR antibodies. The case rested largely on whether the junior party could claim the benefit of the earlier filing date of its grandparent application, which it asserted disclosed the antigen for the antibodies. The Board had found that the junior party's claims lacked written description in the grandparent application and denied them the benefit of the earlier filing date. However, in its decision, the Federal Circuit adopted the position of the court in *Enzo Biochem v. Gen-Probe, Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002), which had adopted the

USPTO Guideline's applicable standard for determining compliance with the written description requirement. More specifically, the Noelle court stated:

> For example, the PTO would find compliance with 112, paragraph 1, for a claim to an isolated antibody capable of binding to antigen X, notwithstanding the functional definition of the antibody, in light of the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature. *Id.*

The Federal Circuit in the Noelle case thus concluded:

> Therefore, based on our past precedent, as long as an applicant has disclosed a "fully characterized antigen," either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen *Id.*.

Thus, conception of an antibody to a protein can occur at the moment the structure, formula, chemical name, or physical properties of said protein are sufficiently known. The erbB-3 protein is well characterized in the present specification, as evidenced by the multiple disclosures and descriptions of the protein found in the specification. In fact, all of the criterion for a "fully disclosed antigen" set forth by the Federal Circuit are found within the present specification: the structure (a 148 kd transmembrane polypeptide with structural features identifying it as a member of the erbB family, page 4, lines 16-18); the formula (the nucleotide and polypeptide are found in SEQ ID NOS: 3 and 4, respectively), the chemical name (erbB-3), and the physical properties (the gene was mapped to human chromosome 12q11-13 and was shown to be expressed as a 6.2 kb transcript, page 4, lines 18-21). Therefore, since the antigen is completely characterized in the specification, the Applicant can then claim an antibody by its binding affinity to that antigen.

Although it is not required by the standards provided above, Applicants point out that they have disclosed a specific antibody capable of binding erbB-3 and not erbB or erbB-2. Coupled with the fact that antibody technology is "well developed and mature," the teaching in section 2163 of the MPEP that "what is conventional or well known to one of ordinary skill in the art need not be disclosed in detail" further proves that the original specification is enabling for the present claims. See *Hybritech Inc. v. Monoclonal Antibodies*, Inc., 802 F.2d at 1384, 231 USPQ at 94. >See also Capon v. Eshhar, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1085 (Fed. Cir. 2005) ("The 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge.... As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution."). If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in ipsis verbis [i.e., "in the same words"] to be sufficient").
The Federal Circuit has explained that a specification cannot always support expansive claim language and satisfy the requirements of 35 U.S.C. 112 "merely by clearly describing one embodiment of the thing claimed." *LizardTech v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1346, 76 USPQ2d 1731, 1733 (Fed. Cir. 2005).

The specification also teaches how to obtain such antibodies (page 16, lines 4-19): "The antibodies...are generated using erbB-3 receptor-related polypeptides or peptides from natural,

recombinant or synthetic chemistry sources. The term 'specific' refers to an erbB-3 antibody capable of binding or otherwise associating nonrandomly with an antigen of erbB-3 such that it does not cross react substantially with other antigens. These antibodies specifically bind to an erbB-3 protein which includes the sequence of such polypeptide. In other words, these antibodies bind substantially only to erbB-3 receptor proteins and not to erbB (EGFR) or erbB-2 proteins."

The issue is whether a person skilled in the art would understand applicant to have invented, and been in possession of, the invention as broadly claimed. In this case, one of skill in the art would have clearly found the specification to have written description for antibodies that bind substantially only to erbB-3 and not to erbB or erbB-2, because the antibody art would have been so well understood, and because applicants were in possession of the corresponding protein (erbB-3), because the specification clearly teaches how to identify other such antibodies, and because an example of such an antibody is given. Applicants therefore respectfully request withdrawal of this rejection.

Claim Rejections – 35 USC § 112, Second Paragraph

Claims 43-46 and 51-59 are rejected as being indefinite because claim 43 recites the limitation "an increase in the level of expression." Applicants respectfully traverse, but appreciate the Examiner's suggestion to amend the claim to recite "greater amount" rather than "increase." In an effort to forward prosecution, claims 43 and 47 have both been amended to remove the phrase "increase" and replace with "greater amount." Applicants respectfully request withdrawal of this rejection.

Claims 43-46 and 51-59 are held as being confusing because the preamble of claim 43 is not drawn to any particular level of erbB-3 gene. Applicant respectfully disagrees, but in an effort to forward prosecution, claim 43 has been amended to recite a method of classifying a cancer as being correlated with a greater amount of expression of an erbB-3 gene as compared to a control. Applicants respectfully request withdrawal of this rejection.

Claims 43-46 and 51-59 are also held as being indefinite in the recitation of the phrase "classifying a cancer as being correlated increased expression of *an* erbB-3 gene." (Emphasis added). The Office Action goes on to state that the use of laboratory designations only to identify a particular expression product renders the claim indefinite. Applicants would like to point out that the term "erbB-3" is not a laboratory designation, but refers instead to a protein, which is characterized by a SEQ ID NO and is well defined in the specification. One of skill in the art would have known what is meant by the term "erbB-3" without any further explanation being given, unlike a random laboratory designation. Also, the protein can be found in Genbank, and has been given an accession number. Furthermore, the Office Action seems to be objecting to the word "an" rather than "the." However, the MPEP, section 2173.05(e) teaches that, "[A] lack of clarity could arise where a claim refers to "said lever" or "the lever," where the claim contains no earlier recitation or limitation of a lever and where it would be unclear as to what element the limitation was making reference." By using the word "an", Applicants were attempting to avoid the word "the" which would not have had proper antecedent basis. Therefore, Applicants respectfully request withdrawal of this rejection.

Claim 43 is also rejected for allegedly not providing a positive process step clearly reciting back to the preamble of the claim. Applicants respectfully disagree, but have amended the claim so that the claim contains a positive process step which correlates to the preamble of the claim. Applicants therefore respectfully request withdrawal of this rejection.

Claim Rejections – 35 USC § 103

Claims 43-46 and 51-59 are rejected for allegedly being unpatentable over Kraus et al. (PNAS, 1993, 90:2900-04).

The Office Action alleges that Kraus teaches a method of classifying a cancer cell as correlated with expression of an erbB-3 gene product. Applicants respectfully disagree. Kraus et al. does not teach or suggest a method of classifying a cancer cell, but rather simply suggests that erbB plays a role in oncogenesis. Applicants therefore respectfully request withdrawal of this rejection.

A credit card payment is being submitted via EFS Web in the amount of $1,050.00, representing the fee for a large entity under 37 C.F.R. § 1.17(a)(3), and a Request for Extension of Time is enclosed. This amount is believed to be correct; however, the Commissioner is

hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.Respectfully submitted,

/Janell T. Cleveland/
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CERTIFICATE OF ELECTRONIC TRANSMISSION UNDER 37 C.F.R. § 1.8			
I hereby certify that this correspondence, including any items indicated as attached or included, is being transmitted via electronic transmission via EFS-Web on the date indicated below.			
Name of Person Mailing (Print/Type)	Janell T. Cleveland		
Signature	/Janell T. Cleveland/	Date	January 7, 2008